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TAGS: ETRD KIPR ECON KTIA PGOV JO
SUBJECT: YEAR 2006 SPECIAL 301 REVIEW: JORDAN

REF: A. AMMAN 1199

¶B. JORDAN COUNTRY SUBMISSION (2/13/06)

1C. AMMAN 1019
1D. STATE 14937
1E. 05 AMMAN 9748
1F. 05 AMMAN 9708

¶G. 05 AMMAN 8330

Classified By: AMBASSADOR DAVID HALE FOR REASONS 1.4 (B, D)

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- (C) SUMMARY: Jordan's leadership has endorsed a vision of intellectual property rights that remains one of the strongest in the Arab world, best captured by Microsoft Corporation's commitment to doing business here. The Government of Jordan (GoJ) is no less committed to IPR protection today, even as the global economy poses new challenges to its trade regime, creates booming free trade zones, and attracts a flood of goods as imports and in the transit trade. Managing IPR protections in this environment has come more easily to some GoJ ministries and agencies than others. For example, the Ministry of Industry and Trade (MOIT) has a well-conceived plan for patent and trademark protections implementation. The Jordan Food and Drug Administration, on the other hand, does not embrace an IPR concept like "data exclusivity" as a primary mission and, to date, has been slow to learn and act (Refs C, E). Post reports below on the JFDA case, especially as it relates to PhRMA's submission on Jordan to the Special 301 Review committee. As reported previously (Refs A, F, G), the GoJ has the political will to tackle most IPR issues and is addressing most shortcomings with seriousness, a collective will, and proposed plans for action (Ref A).
- 12. (SBU/NOFORN) SUMMARY CONTINUED: In the area of pharmaceutical IPR protections, however, unless events over the weeks ahead witness a significant turnaround, Jordan is not currently providing adequate and effective protection for intellectual property rights and may be denying fair and equitable market access to IP holders. For these reasons, post recommends Jordan for Watch List status in the Special 301 Review, pending resolute and immediate GoJ actions to reverse the current circumstances. END SUMMARY.

The PhRMA Submission on IPR

13. (C/NF) PhRMA member companies on the ground have made clear their manifest problems that stem largely from a non-transparent regulator - the JFDA - that provides no clear guidance regarding its actions. To date, the regulator seems content with the prospect that generic companies should have access to originator-company drugs as soon as possible, and that any obligation to "protect" data exclusivity should come from outside the regulatory framework, e.g. court decisions (Ref E). Generic companies are represented in the JFDA's decision-making process, which to date has produced these unclear decisions. COMMENT: The likely motivation for the JFDA's stance is to keep drug costs for the average Jordanian low. Additionally, the JFDA has trouble keeping an arms-length relationship with its domestic (overwhelmingly generics) pharmaceutical industry. The JFDA has been accused by some in PhRMA of engaging in stall tactics; this may be an uncharitable assessment of a young organization. Given that some of these unresolved issues go back to 2003, at the very least chronic indecision has plagued what amounts to an ungovernable bureaucracy in the JFDA. END COMMENT.

- $\P 4$. (SBU) Clear, precise regulations and instructions on the issues raised by PhRMA are required.
- 15. (C/NF) The JFDA continues to engage PhRMA members on their issues, but it is difficult to discern the intent -- after hearing of PhRMA's Special 301 submission, the JFDA DG reportedly told one local PhRMA member (protect) that there was no further reason to engage in dialogue. COMMENT: In our view, local PhRMA companies are at times overwhelmed by their regulator. We believe a digital video conference between the JFDA and the USTR, to be held on February 27, will help clear the air and set the regulator back on track to a more positive dialogue. END COMMENT.
- 16. (SBU) The issues in play need to be removed from the realm of the regulator-and-regulated, and discussed at a higher plane in which the USG emphasizes that these are trade commitments having binding legal force, since the FTA and annexes were published as law in Jordan's Official Gazette on July 16, 2001. The GoJ also needs clarity on USG definitions and emphases arising from the Free Trade Agreement. A first effort represented by a non-paper from USTR delivered to the GoJ on February 12 (Ref C) is a start in this direction.

Market Access

17. (SBU/NF) PhRMA's complaint about the JFDA's pharmacovigilance rules is beyond the realm of mere trade. While it is potentially a technical barrier, prevailing practices regarding drug safety cannot be taken lightly, so long as they are uniformly applied. The JFDA has noted to the embassy that PhRMA applicants can start a drug registration file prior to the drug's approval and release, and that the pharmacovigilance can commence at the time of initial application. As a result, the actual time "lost" on the market would then be less than a year and could be as little as six months. Post notes that Jordan supports the growing domestic clinical research organizations (CRO's) that conduct modern, statistically relevant clinical trials to determine drug safety and efficacy; the GoJ's questioning their relevance and/or accuracy is not consistent with this approach. The net public health effect resulting from the delay cannot be very significant.

Price Controls

18. (SBU) Jordan's drug price controls are inconsistent with the Free Trade Agreement's singular purpose to liberalize trade and open markets. At the very least, the changing and inconsistent pricing rules applied by the JFDA need to be amended into one set of consistent, understandable criteria.

Possible Actions

19. (C/NF) A critical issue is whether the Government of Jordan has the requisite political will to accomplish the

tasks necessary to meet FTA commitments in this area. Instructions in Ref (D) inquire if any "possible actions" undertaken by Jordan to redress inadequacies could be completed prior to completion of the Special 301 review (on or about April 30). In theory, such actions could be completed - the cabinet would approve new regulations, and follow-on instructions could be approved to meet the regulations. The JFDA's history, however, does not exemplify rapid action, especially when the continued existence of "gray areas" in the rules of the game benefit a powerful domestic industry.

¶10. (SBU) It would appear that at least one regulation on "new uses" is nearer to being implemented, according to the GoJ submission to the USTR (Ref B, submitted via email). Post will take a wait-and-see attitude regarding possible comprehensive redress by the GoJ of the problems outlined by PhRMA, and would recommend being direct and unflinching in pressing for immediate action before the Special 301 review is completed.

Ongoing Areas of Review

- 111. (SBU) Setting aside the PhRMA case, despite some gaps in both the legal-regulatory framework and in the government inter-agency mission definitions (Refs A, F, G), Jordan is generally committed to adequate and effective protection for intellectual property rights. Following is our overall assessment of specific areas of concern:
- A) Optical Media Piracy (CDs, VCDs, DVDs)

Most of the pirated optical media in Jordan still appear to enter from neighboring states or from overseas. (The Embassy's assessment is based on anecdotal information, confirmed by knowledgeable observers). There are no large factories producing optical disks in Jordan, according to the president of the Jordan Intellectual Property Association. However, there are more frequent reports of "mom-and-pop" operations burning copies of good-quality masters. Enforcement officials report they are attempting to identify and interdict the sources of these masters by observing the distribution process. Unlike last fall, when different stake-holders had differing views on optical media piracy, the GoJ is now coming to a more cohesive view of the problem. Solutions should be implemented as early as June. Other solutions such as stronger ex officio border measures are actively being considered and should be in place by the end of the year. NOTE: These measures will require the passage of amendments to existing laws, which explains the additional time required. END NOTE.

B) Use/Procurement of Government Software

Since the publication of a government directive in 2004 to address an already dwindling problem, Embassy has received fewer reports of improper use of software in government offices.

C) TRIPS, FTA Implementation, other IP-Related Issues

A comprehensive study of the GOJ's IPR compliance, completed in January by the USAID Achievement in Market Friendly Initiatives and Results (AMIR) program (delivered to Washington agencies on February 1, Ref A), presented a thorough analysis of the GoJ's implementation of its various international IPR protection obligations. Gaps have been identified, and two committees - in the Ministry of Industry and Trade (MOIT) and in the Ministry of Culture-controlled National Library - are considering next steps. AMIR is working with the GoJ agencies concerned, and has already begun to circulate a rough draft plan of action. Recommended amendments to patent and trademark legislation are already in train.

Post is not aware of any legislation or regulations related to domestic protection of traditional knowledge or expressions of folklore, or addressing issues related to genetic resources and access and benefit sharing.

Efforts on data protection are discussed in Refs (C, E) and in paragraphs 2-6 of this message (see above).

Interagency efforts against counterfeited goods (virtually all imported) are being implemented and/or monitored through the MOIT's IPR committee. Jordanian Customs continues to interdict counterfeits at the borders, with generally good results. Anecdotal evidence indicates counterfeit goods continue to appear on store shelves. Proliferating free zones have presented unique law enforcement challenges to anti-counterfeiting efforts, and some modest low-level corruption is occasionally reported. Embassy has witnessed good private-public partnership in this area - significant cases are brought to justice. Enhancement of the ex officio border measures (see para 11A, above) will be critical. A consensus has emerged to give the Jordan Institute of Standards and Metrology (JISM) a stronger role at the border to detect and intercept counterfeits.

D) Enforcement

As reported (Ref A), enforcement efforts are hampered on several fronts, but the stake-holders over the past three months have come to a better understanding of the challenges, and appear genuinely committed to bringing enforcement to a new level of effectiveness in Jordan.

Treaties

(SBU) While Jordan has ratified the WIPO treaties and the GoJ has held workshops on their implementation, post believes the GoJ National Library must now publish regulations and or instructions to facilitate their fullest implementation (Ref A). The AMIR program is engaged in discussions with the National Library on drafting such a regulatory framework. Other steps to fill gaps in international obligations are being taken, as outlined in paragraph 11C, above.

At all levels of the Jordanian government, post has made known its serious commitment to the fullest possible enforcement of FTA obligations related to IPR protections.

Training

113. (U) The USAID AMIR program continues to be the key provider of training to Jordan's IPR policy-makers and enforcers. Over the past year up until the present, AMIR has supported 25 IPR-related events including scores of GoJ officials. Topics have covered IPR awareness, advocacy, enforcement and related IPR intelligence vetting.

AMIR has committed to sponsoring 15 Jordanian participants at 8 USPTO IPR training programs in the U.S. and four other officials at WIPO, ASTM and other conferences in the U.S.

Post has also reached out to USPTO to secure some additional support for training slots at regional IPR training exercises for Jordanian Judges (Dubai) and prosecutors (Oman). USPTO has been a valuable resource in these efforts.

USAID's democracy and governance program is attempting to work with the GoJ Judicial Council to build more judicial training related to IPR. A new judicial training program of the DOC's Commercial Law and Development Program is also slated to have an IPR component.

114. (SBU/NF) One limitation to post's IPR-related programs are MEPI restrictions on funding - Jordan is often among the countries not/not able to receive MEPI funding for USPTO and other IPR programs. With the exclusion of highly specialized pharmaceutical problems, we believe that Jordan holds importance as a one of the region's solid performers, especially with its growing internal commitment to moving to a new level of IPR legal-regulatory controls and enforcement. Some sort of informal match of funds to post expenditures from the MEPI program could help support this effort to achieve regional IPR goals sooner.

Post is exploring a visit by Library of Congress (LOC) personnel and, if a first visit proves successful, would appreciate follow-on funding for more programming bringing LOC visitors here or sending GoJ officials to the Library.

Finally, the GoJ National Library and other enforcement personnel could benefit from the TDY seconding of an IPR law enforcement official from the U.S. who would work behind the scenes to increase IPR enforcement capacity. HALE